

COVID-19 Vaccine Information Brief

January 14, 2022

Changes to the document from the previous version are highlighted in yellow.

IMPORTANT/NEW COVID-19 Vaccine Information

- COVID-19 Primary Vaccination
- Interim Clinical Considerations for Use of COVID-19 Vaccines - Updated
- Pfizer-BioNTech and Moderna Provider and Recipient/Caregiver Fact Sheets Updates
- Pfizer COVID-19 Vaccine Medical Updates on Current & Immunization Site Training
- CDC Definition of “Up to Date” with COVID-19 Vaccination
- Interim Clinical Considerations for Use of COVID-19 Vaccines - Updated
- Pfizer Shelf-Life Extension Approved
- COVID-19 Vaccine Quick Reference Guide
- Changes to the COVID-19 Vaccine Administration Dashboard
- Vaccination Supplies
- Report of Health Care Provider Recommendation for COVID-19 Vaccination
- Pfizer Product Overview
- Vaccine Expiration Date Resources
- V-Safe After Vaccination Health Checker

COVID-19 Primary Vaccination

The vaccines are still the BEST defense against COVID, including the Omicron and Delta variants. Getting people vaccinated with a COVID-19 primary vaccine series remains the highest priority and is fundamental to reducing COVID-related morbidity and mortality. CDC's updated recommendation to shorten the length of time between the completion of the primary COVID vaccination series (Pfizer or Moderna) and the booster dose may help with waning immunity. The very fast spread of the Omicron variant across the U.S. and around the world adds urgency to the need for both primary and booster doses.

All COVID-19 vaccines currently approved or authorized in the United States remain effective against severe disease, hospitalization and death. Persons of all ages who have received a primary vaccine series are much less likely than unvaccinated persons to become infected with SARS-CoV-2 and to require hospitalization or die because of COVID-19.

Interim Clinical Considerations for Use of COVID-19 Vaccines - Updated

[Interim Clinical Considerations](#) have been updated. A summary of recent changes (last updated January 6, 2022):

- Updated guidance for use of Pfizer-BioNTech COVID-19 Vaccine as a booster in people ages 12–17 years
- Updated guidance for administration of a COVID-19 vaccine booster dose at least 5 months after completion of an mRNA vaccine (Pfizer-BioNTech or Moderna) primary series
- Updated guidance for use of an additional primary dose for moderately or severely immunocompromised people ages 5–11 years who received a Pfizer-BioNTech vaccine primary series

- Updated recommendations for people who received COVID-19 vaccines outside the United States that are not FDA-authorized or approved

Key points

- COVID-19 vaccines currently approved or authorized by FDA [are effective](#) in preventing serious outcomes of COVID-19, including severe disease, hospitalization, and death.
- COVID-19 primary series vaccination is recommended for everyone ages 5 years and older in the United States for the prevention of coronavirus disease 2019 (COVID-19).
- In most situations, Pfizer-BioNTech or Moderna COVID-19 vaccines are preferred over the Janssen COVID-19 Vaccine for primary and booster vaccination.
- An additional primary mRNA COVID-19 vaccine dose is recommended at least 28 days later for moderately or severely immunocompromised people ages 5 years and older who received a 2-dose mRNA vaccine primary series.
- A booster dose of COVID-19 vaccine is recommended for everyone ages 12 years and older (Pfizer-BioNTech for ages 12–17; an mRNA vaccine preferred for ages 18 years and older):
 - At least 5 months after completion of an mRNA vaccine (Pfizer-BioNTech or Moderna) primary series.
 - At least 2 months after completion of a Janssen COVID-19 Vaccine primary dose.
- Efforts to maximize the proportion of people in the United States who are [up to date](#) with their COVID-19 vaccines remain critical to ending the COVID-19 pandemic.
- These clinical considerations provide additional information to healthcare professionals and public health officials on use of COVID-19 vaccines.
- **Children 5-11 years old are not recommended to get a booster dose at this time.**

Who Can Get a Booster Shot

IF YOU RECEIVED Pfizer-BioNTech	Who should get a booster: <ul style="list-style-type: none"> Everyone 12 years and older 	When to get a booster: <ul style="list-style-type: none"> At least 5 months after completing your primary COVID-19 vaccination series 	Which booster can you get: <ul style="list-style-type: none"> Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) are preferred in most* situations Teens 12–17 years old may only get a Pfizer-BioNTech COVID-19 vaccine booster
IF YOU RECEIVED Moderna	Who should get a booster: <ul style="list-style-type: none"> Adults 18 years and older 	When to get a booster: <ul style="list-style-type: none"> At least 5 months after completing your primary COVID-19 vaccination series 	Which booster can you get: <ul style="list-style-type: none"> Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) are preferred in most* situations
IF YOU RECEIVED Johnson & Johnson's Janssen*	Who should get a booster: <ul style="list-style-type: none"> Adults 18 years and older 	When to get a booster: <ul style="list-style-type: none"> At least 2 months after receiving your J&J/Janssen COVID-19 vaccination 	Which booster can you get: <ul style="list-style-type: none"> Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) are preferred in most* situations

*Although mRNA vaccines are preferred, J&J/Janssen COVID-19 vaccine [may be considered in some situations](#).

Pfizer-BioNTech and Moderna Provider and Recipient/Caregiver Fact Sheets Updates

FDA Provider and Recipient/Caregiver Fact Sheets have been updated to reflect amendments the FDA recently made to the Emergency Use Authorizations (EUA) for Pfizer-BioNTech and Moderna COVID-19 vaccines. The updated Fact Sheets contain additional details and can be found at [Comirnaty and Pfizer-BioNTech COVID-19 Vaccine | FDA](#) and [Moderna COVID-19 Vaccine | FDA](#).

COVID-19 [Pfizer BioNTech EUA Recipient/Caregiver Fact Sheet - 12 years and older](#):

- Booster dose is now authorized for individuals ages 12 to 15 years.
- The interval from primary series last dose to booster dose has been reduced from six months to five months for those who received a primary series of the Pfizer vaccine.

COVID-19 [Pfizer BioNTech EUA Recipient/Caregiver Fact Sheet - Pediatric](#):

- A third dose is now authorized for immunocompromised individuals ages five to 11 years with an interval of 28 days after their second shot.
 - Note: a new CPT administration code is needed for this third dose. The AMA will publish the new code on their [website](#) by January 14.

COVID-19 [Moderna EUA Recipient/Caregiver Fact Sheet - 18 Years and Older](#):

- The interval from primary series last dose to booster dose has been reduced from six months to five months.

Pfizer COVID-19 Vaccine Medical Updates on Current & Immunization Site Training

Pfizer Vaccines US Medical Affairs continues to host daily *Medical Updates & Immunization Site Training for All Providers with a Focus on Emergency Use Authorization of the Pfizer-BioNTech COVID-19 Vaccine for Children 5 through 11 Years of Age*.

- In addition to Medical Updates, sessions will focus on the Storage, Handling, & Administration for currently available vaccine presentations
- These sessions will be updated to reflect new information and changes that evolve. Such updates will be identified at the start of each session and further explained during each presentation.

Please click on the links below to join the sessions at the designated times.*

Date & Time	Password
Attendee link – Tues January 18 - 3pm ET	FJvmeG327W
Attendee link – Wed January 19 - 12pm ET	kMapPATn986
Attendee link – Thurs January 20 - 12pm ET	grB3WCzru23
Attendee link – Tues January 25 - 3pm ET	AQqwYfKE522
Attendee link – Wed January 26 - 12pm ET	2pSQT324TdC
Attendee link – Thurs January 27 - 12pm ET	yVDHYiaF828

CDC Definition of “Up to Date” with COVID-19 Vaccination

CDC has updated its website to inform the ongoing COVID-19 response about being “up to date” with COVID-19 vaccinations as well as providing the background that informed CDC’s update on quarantine and isolation.

CDC is updating its webpage to align with standard language CDC uses about other vaccinations, CDC will now use the phrase “up to date” when talking about COVID-19 vaccination. CDC recommends individuals stay “up to date” by receiving any additional doses they are eligible for, according to CDC’s recommendations, to ensure optimal protection against COVID-19. **The technical definition of “fully vaccinated” – two doses of an mRNA vaccine or one dose of the J&J vaccine – has not changed.** Individuals are considered fully vaccinated once they have received the primary series. This change is reflected on CDC webpages. The following link will reflect this change when updated: [When You’ve Been Fully Vaccinated | CDC](#)

Pfizer Shelf-Life Extension Approved

FDA has approved a shelf-life extension for the Pfizer Pediatric vaccine (Orange cap, 5-11 YO, diluent required) and the soon to be available Adol/Adult Tris (Gray Cap, age 12+, no diluent). This approval may be found at [Healthcare Providers for 5-11 years of age, orange cap \(must dilute\) \(fda.gov\)](#) ; [Healthcare Providers for 12 years of age and older, gray cap \(no dilution\) \(fda.gov\)](#)) and takes effect immediately. This extension applies to frozen (ULT) inventories only.

The date printed on the Pfizer Pediatric (orange cap) and Adult/Adolescent (gray cap, 12+, no diluent) vaccine vials indicate the manufacture date and NOT the expiration date.

Originally, the expiration date was 6 months from the manufacture date. The expiration date for Pfizer orange and gray cap vaccine has now been extended to 9 months (while held at ULT frozen.) The Fact Sheets for both orange and gray cap vials provided by the FDA now reads, “regardless of storage conditions, vaccines should not be used after 9 months from the date of manufacture printed on the vial and cartons”. The updated expiry dates for both the orange and gray cap vials based on 9 months from the date of manufacture are provided below.

Printed Manufacturing Date	9-Month Expiry Date*
06/2021	Feb. 28, 2022
07/2021	Mar. 31, 2022
08/2021	Apr. 30, 2022
09/2021	May 31, 2022
10/2021	Jun. 30, 2022
11/2021	July. 31, 2022
12/2021	Aug. 31, 2022
01/2022	Sept. 30, 2022
02/2022	Oct. 31, 2022

*Date of expiration always falls on the last day of the month

The QR code provided on the Pfizer Pediatric Vaccine carton provides a link to the EUA but does not provide information on expiration dates.

Please follow EUA recommendations for storage:

Pfizer 5 through 11 years of age formulation

- If not previously thawed at 2°C to 8°C (35°F to 46°F), allow vials to thaw at room temperature [up to 25°C (77°F)] for 30 minutes.
- Pfizer-BioNTech COVID-19 Vaccine multiple dose vials with orange caps and labels with orange borders may be stored at room temperature [8°C to 25°C (46°F to 77°F)] for a total of 12 hours prior to dilution.
- After dilution, the vial should be held between 2°C to 25°C (35°F to 77°F). Vials should be discarded 12 hours after dilution.

Pfizer 12 years and older formulation

- Frozen vials may be stored in an ultra-low temperature freezer at -90°C to -60°C (-130°F to -76°F). Do not store vials at -25°C to -15°C (-13°F to 5°F). Once vials are thawed they should not be refrozen.
- Vials may be transferred to the refrigerator [2°C to 8°C (35°F to 46°F)], thawed and stored for up to 10 weeks. The 10-week refrigerated expiry date should be recorded on the carton at the time of transfer. A carton of 10 vials may take up to 6 hours to thaw at this temperature.

Regardless of storage condition, vaccines should not be used after 9 months from the date of manufacture printed on the vial and cartons.

All Pfizer updated Fact Sheets may be found at:

- <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine#additional>
 - [Healthcare Providers for 5-11 years of age, orange cap \(must dilute\) \(fda.gov\)](#)
 - [Healthcare Providers for 12 years of age and older, gray cap \(no dilution\) \(fda.gov\)](#)
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COVID-19 Quick Reference Guide

The quick reference guide provides basic information on the proper storage, preparation, and administration of the currently authorized COVID-19 vaccine products in the United States. It is now updated with Pfizer Peds. For additional information and detailed clinical guidance go to the manufacturers' website and CDC's webpages listed on the guide.

Link to guide:

<https://www.cdc.gov/vaccines/covid-19/downloads/covid19-vaccine-quick-reference-guide-2pages.pdf>

Changes to the Iowa COVID-19 Vaccine Administration Dashboard




Pediatric Pfizer (5-11) and Booster dose vaccine administration data were added to the [COVID-19 Vaccine Administration Dashboard](#) on December 8, 2021. These data had an impact on the total number of doses administered statewide. The Pfizer (5-11) vaccine data will impact the series initiating/completing two-dose vaccination measures as well as total vaccine series completed. The booster doses are defined as any additional dose after completion of a primary series. The booster doses will not have any impact on the total vaccine series completed data.

Vaccination Supplies

The State of Iowa has recently obtained a limited quantity of individual 25 Gauge 5/8 inch safety needles, 1cc syringes, and a supply of combination 1 inch safety needles and 1 CC syringes. These vaccination supplies are available upon request by Local Public Health Agencies. These supplies are intended to be a back-up resource, the vaccine ancillary kits delivered with the vaccine will have 1 or 1^{1/2} inch needles, however IDPH is aware many prefer the 5/8 inch needles for the younger pediatric doses.

LPHAs should contact their [county emergency management coordinator](#) to request these supplies. County Emergency Managers will enter an individual WebEOC Mission for each LPHA requesting the needles and syringes.

Pfizer Product Overview

COVID-19 Vaccine Presentations			
	 Purple Cap	 Gray Cap	 Orange Cap
Age	12+	12+	5 - <12
Formulation	PBS / Sucrose	Tris / Sucrose*	Tris / Sucrose*
Diluent Required	YES (1.8mL)	NO (DO NOT DILUTE)	YES (1.3 mL)
Dosage	30 mcg	30 mcg	10 mcg
Doses per Vial	6 doses	6 doses	10 doses
Injection Volume	0.3 mL	0.3 mL	0.2 mL
Storage in ULT Freezer (-90°C to -60°C)	Up to 9 months	Up to 6 months*	Up to 6 months*
Storage in Refrigerator (2°C to 8°C)	Up to one month	Up to 10 weeks*	Up to 10 weeks*
Storage in Freezer (-25°C to -15°C)	Up to 2 weeks	N/A	N/A

Vaccine Expiration Date Resources

Always be sure to check the manufacturer's website to obtain the most up-to-date expiration dates for COVID-19 vaccines. This is necessary for J&J vaccine as well as Moderna and Pfizer COVID-19 vaccines. It is important for healthcare providers to update vaccine expiration dates in IRIS. Questions regarding IRIS vaccine inventory and adjusting expirations dates can be directed to the IRIS Helpdesk at 800-374-3958.

For EUA COVID-19 vaccines that do not have a final expiration date, the CDC has set an expiration date of 12/31/2069 to serve as a placeholder date. Such vaccines have a dynamic expiration date, which can change over time as additional stability data become available. This placeholder date, which is far in the future, is intended to serve as a prompt for the provider to check the latest expiry information on the manufacturer's website. **It is important for healthcare providers to update vaccine expiration dates in IRIS.**

Janssen COVID-19 vaccine: The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:

- Scan the QR code located on the outer carton, or
- Call 1-800-565-4008, or
- Go to www.vaxcheck.inj/

Moderna COVID-19 vaccine:

The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:

- Scan the QR code located on the outer carton, or

- Go to www.modernatx.com/covid19vaccine-eua/

The new Pfizer Adult/Adolescent formulation (gray cap) and Pediatric COVID-19 vaccine (orange cap):

- Pfizer does not have an expiration date look up tool for these vaccines
- Formulation does NOT have expiration printed on vial
- Instead, each vial has the lot number and date of manufacture printed on the label
- Date on the label is NOT the expiration date
- Expiration date of the Pfizer pediatric COVID-19 vaccine is 6 months from the manufacturer date
 - Example: A vial with a manufacture date of 8/2021 includes August. It does not start in September. Expiration date would be Jan 31, 2022.

CDC's [COVID-19 Vaccine Expiration Date Tracking Tool](#) can help providers keep track of the expiration date by lot number.

J&J/Janssen		Moderna		Pfizer	
Lot Number	Expiration	Lot Number	Expiration	Lot Number	Expiration
1822786	2/6/2022	079C21A	1/16/2022	FC3180	1/31/2022
1822809	3/7/2022	019F21A	1/20/2022	FD8448	1/31/2022
215C21A	3/8/2022	015F21A	1/20/2022	EY0584	1/31/2022
1822811	3/20/2022	006D21A	1/21/2022	FC3184	1/31/2022
203F21A	3/21/2022	010D21A	1/21/2022	FA7485	1/31/2022
204F21A	3/22/2022	020F21A	1/21/2022	FC3183	1/31/2022
218C21A	4/9/2022	011D21A	1/22/2022	FD0809	1/31/2022
1855194	4/9/2022	013F21A	1/22/2022	FC3182	1/31/2022
211D21A	4/11/2022	048F21A	1/22/2022	FC3181	1/31/2022
213D21A	4/11/2022	012D21A	1/23/2022	FD0810	2/28/2022
220C21A	4/11/2022	049F21A	1/23/2022	30125BA	2/28/2022
1855191	4/11/2022	050F21A	1/24/2022	EY0581	2/28/2022
208D21A	4/24/2022	025D21A	1/25/2022	FD7220	2/28/2022
1855835	4/27/2022	026D21A	1/26/2022	EY0582	2/28/2022
1855190	4/27/2022	022F21A	1/27/2022	30135BA	2/28/2022
		072F21A	1/29/2022	FE3590	2/28/2022
		032F21A	1/29/2022	30145BA	2/28/2022
		035F21A	1/29/2022	FD7218	2/28/2022
		039D21A	2/1/2022	30130BA	2/28/2022
		038F21A	2/1/2022	FE3592	2/28/2022
		939908	2/1/2022	FE3594	2/28/2022
		065F21A	2/4/2022		
		058F21A	2/5/2022		
		042D21A	2/7/2022		
		069F21A	2/7/2022		

V-Safe After Vaccination Health Checker

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after an individual receives a COVID-19 vaccination. V-safe web pages feature information on how to register and complete a v-safe health check-in (including step-by-instructions with images), troubleshooting, FAQs, and contact information for technical support. These web pages will be continuously updated with additional resources.

- V-safe information sheet and poster: Posted on the Vaccine webpage and available in 5 languages: English, Spanish, Korean, Vietnamese, and Simplified Chinese
- [V-safe after vaccination health checker website](#)
- [V-Safe Print Resources](#)
- [Vaccine Adverse Event Reporting System \(VAERS\)](#)